

INTERNATIONAL STANDARD

CONSOLIDATED VERSION

**Medical electrical equipment -
Part 2-4: Particular requirements for the basic safety and essential performance
of cardiac defibrillators**

get full document from standards.iteh.ai



THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2026 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

IEC Secretariat
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search -

webstore.iec.ch/advsearchform

The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee, ...). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished

Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

IEC Products & Services Portal - products.iec.ch

Discover our powerful search engine and read freely all the publications previews, graphical symbols and the glossary. With a subscription you will always have access to up to date content tailored to your needs.

Electropedia - www.electropedia.org

The world's leading online dictionary on electrotechnology, containing more than 22 500 terminological entries in English and French, with equivalent terms in 25 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

Warning! Make sure that you obtained this publication from an authorized distributor.

CONTENTS

FOREWORD	3
INTRODUCTION to Amendment 2	6
201.1 Scope, object and related standards	7
201.2 Normative references	9
201.3 Terms and definitions	9
201.4 General requirements	12
201.5 General requirements for testing of ME EQUIPMENT	13
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	13
201.7 ME EQUIPMENT identification, marking and documents	13
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	18
201.9 Protection against MECAHNICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	25
201.10 Protection against unwanted and excessive radiation HAZARDS	25
201.11 Protection against excessive temperatures and other HAZARDS	25
201.12 * Accuracy of controls and instruments and protection against hazardous outputs	27
201.13 HAZARDOUS SITUATIONS and fault conditions	29
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	29
201.15 Construction of ME EQUIPMENT	30
201.16 ME SYSTEMS	34
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	34
201.101 * Charging time	34
201.102 INTERNAL ELECTRICAL POWER SOURCE	39
201.103 * Endurance	41
201.104 * SYNCHRONIZER	42
201.105 * Recovery of the MONITOR and/or ECG input after defibrillation	42
201.106 * Disturbance to the MONITOR from charging or internal discharging	46
201.107 * Requirements for RHYTHM RECOGNITION DETECTOR	47
201.108 DEFIBRILLATOR ELECTRODES	48
201.109 * External pacing (U.S.)	51
202 * Electromagnetic compatibility – Requirements and tests	55
Annexes	59
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS	60
Annex AA (informative) Particular guidance and rationale	62
Annex BB (informative) Mapping between the elements of the second edition of IEC 60601-2-4 and IEC 60601-2-4:2010	78
Bibliography	83
Index of defined terms used in this particular standard	84
Figure 201.101 – Dynamic test for limitation of energy from different parts of the ME EQUIPMENT	20
Figure 201.102 – Allowed current versus applied test voltage	24

Figure 201.103 – Examples of cord anchorages that require testing	33
Figure 201.104 – Test apparatus for flexible cords and their anchorages	34
Figure 201.105 – Arrangement for test of recovery after defibrillation	44
Figure 201.106 – Arrangement of monitoring electrodes on sponge	45
Figure 201.107 – Arrangement for recovery test after defibrillation	45
Figure 201.108 – Arrangement for test of disturbance from charging and internal discharging	47
Figure 201.109 – Test circuit for offset instability/internal noise determination	47
Figure 201.110 – Test circuit for DEFIBRILLATOR overload test of pacing output circuitry	55
Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements	13
Table 201.102 – RHYTHM RECOGNITION DETECTOR categories	47
Table 201.C.101 – Marking on the outside of a CARDIAC DEFIBRILLATOR or its parts.....	60
Table 201.C.102 – Marking of controls and instruments of a CARDIAC DEFIBRILLATOR	60
Table 201.C.103 – ACCOMPANYING DOCUMENTS, general	60
Table 201.C.104 – ACCOMPANYING DOCUMENTS, instructions for use	60
Table 201.C.105 – ACCOMPANYING DOCUMENTS, technical description	61
Table BB.1 – Mapping between the elements of the second edition of IEC 60601-2-4 and IEC 60601-2-4:2010	78

Sample Document

get full document from standards.iteh.ai

INTERNATIONAL ELECTROTECHNICAL COMMISSION

Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at <https://patents.iec.ch>. IEC shall not be held responsible for identifying any or all such patent rights.

This consolidated version of the official IEC Standard and its amendments has been prepared for user convenience.

IEC 60601-2-4 edition 3.2 contains the third edition (2010-12) [documents 62D/857/FDIS and 62D/878/RVD], its amendment 1 (2018-02) [documents 62D/1549/FDIS and 62D/1555/RVD] and its amendment 2 (2026-09) [documents 62D/2317/FDIS and 62D/2327/RVD].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendments 1 and 2. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

International standard IEC 60601-2-4 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition constitutes a technical revision, revised to structurally align it with IEC 60601-1:2005 and to implement the decision of IEC SC 62A that the clause numbering structure of particular standards written to IEC 60601-1:2005 would adhere to the form specified in ISO/IEC Directives, Part 2:2004. The aim of this third edition is to bring this particular standard up to date with reference to the third edition of the general standard through reformatting and technical changes.

The principle technical changes are as follows:

- 201.8.8.3, test 4: added additional test options;
- Figure 201.105: provided example of stainless steel plates. Added note for 10 Hz generator or shockable rhythm generator;
- Figure 201.101: Changed orientation of the lower diode at the oscilloscope connection;
- 202.6.1, .2, .4: "Additions" and "Replacements" corrected to be as originally intended;
- 201.101.1: Clarified preconditioning of a non-rechargeable battery;
- 201.3.207: Clarified definition of DUMMY COMPONENT;
- 201.15.4.101: In paragraph b), added reduced flex requirements for sterilizable internal paddles with specified limit on sterilization cycles;
- 201.15.4.3.103: Added an option for devices having non-changeable pre-programmed energy-setting sequences;
- 201.102.3.1, 2: Changed from specified defibrillation cycles to use of pre-programmed defibrillation sequence;
- 202.6.2.2.1: Changed ESD discharge sequence to match IEC 60601-1-2, third edition.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this document and its amendments will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

Sample Document

get full document from standards.iteh.ai

INTRODUCTION to Amendment 2

Amendment 2 to the International standard IEC 60601-2-4 has been prepared by IEC subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems in medical practice. Amendment 2 changes is to align to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020.

Sample Document

get full document from standards.iteh.ai

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of CARDIAC DEFIBRILLATORS, hereafter referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This particular standard does not apply to implantable DEFIBRILLATORS, remote control DEFIBRILLATORS, ~~external transcutaneous pacemakers~~, or separate stand-alone cardiac monitors (which are standardized by IEC 60601-2-27:2011 [2]²). Cardiac monitors which use separate ECG monitoring electrodes are not within the scope of this standard unless they are used as the sole basis for AED rhythm recognition detection or beat detection for synchronized cardioversion. DEFIBRILLATOR electrodes as described in 201.108 can also be used for ECG monitoring; however, due to the larger electrode area, the requirements of IEC 60601-2-27 are not applicable for DEFIBRILLATOR ELECTRODES.

Defibrillation waveform technology is evolving rapidly. Published studies indicate that the effectiveness of waveforms varies. The choice of a particular waveform including waveshape, delivered energy, efficacy, and safety has been specifically excluded from the scope of this standard.

However, due to the critical importance of the therapeutic waveform, comments have been added to the rationale which addresses considerations in waveform selection.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for cardiac defibrillators as defined in 201.3.202.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

¹ The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

² Numbers in square brackets refer to the bibliography.

IEC 60601-1-2 applies as modified in Clause 202. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 83.

Clause 2 of the general standard applies, except as follows:

Amendment:

IEC 60601-1-2:~~2007~~2014, *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic ~~compatibility~~ disturbances - Requirements and tests*
IEC 60601-1-2:2014/AMD1:2020

Addition:

IEC 61000-4-2, *Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test*

IEC 60601-1:2005, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-1-8:2006, *Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
IEC 60601-1-8:2006/AMD1:2012
IEC 60601-1-8:2006/AMD2:2020

IEC TR 61000-2-5, *Electromagnetic compatibility (EMC) - Part 2-5: Environment - Description and classification of electromagnetic environments*

IEC 61000-4-3, *Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test*

IEC 61000-4-4, *Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test*

IEC 61000-4-5:2014, *Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test*

IEC 61000-4-8, *Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test*

ISO 15223-1:~~2007~~2021, *Medical devices - Symbols to be used with ~~medical device labels, labelling and~~ information to be supplied by the manufacturer - Part 1: General requirements*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, IEC 60601-1-2:2014, and IEC 60601-1-2:2014/AMD1:2020 apply, except as follows:

Addition:

NOTE An index of defined terms is found beginning on page 84.

201.3.201**AUTOMATED EXTERNAL DEFIBRILLATOR
AED**

DEFIBRILLATOR that, once activated by the OPERATOR, analyses the ECG obtained from electrodes placed on the patient's skin identifies shockable cardiac rhythms, and automatically operates the DEFIBRILLATOR when a shockable rhythm is detected, hereinafter referred to as an AED

NOTE AEDs may provide varying levels of automation and be referred to by various terms. A semi-automatic DEFIBRILLATOR requires manual shock activation. A fully automatic DEFIBRILLATOR will provide shock without OPERATOR intervention.

201.3.202**CARDIAC DEFIBRILLATOR**

MEDICAL ELECTRICAL EQUIPMENT intended to normalize the rhythm of the heart by an electrical pulse via electrodes applied either to the PATIENT's skin with external electrodes or to the exposed heart with internal electrodes

NOTE 1 A CARDIAC DEFIBRILLATOR can be referred to in this standard as a DEFIBRILLATOR or as ME EQUIPMENT.

NOTE 2 Such ME EQUIPMENT may also include other monitoring or therapeutic functions (e.g. transcutaneous pacing).

201.3.203**CHARGING CIRCUIT**

circuit within the DEFIBRILLATOR intended for charging the ENERGY STORAGE DEVICE. This circuit includes all parts conductively connected to the ENERGY STORAGE DEVICE during the charging period

NOTE The CHARGING CIRCUITS for defibrillation and pacing functions may be separate or combined.

201.3.204**DEFIBRILLATOR ELECTRODE**

electrode intended to deliver an electrical pulse ~~to the PATIENT~~ for the purpose of cardiac defibrillation and which may also be used to provide transcutaneous pacing and other monitoring functions

NOTE DEFIBRILLATOR ELECTRODES ~~may also provide other monitoring (e.g. ECG acquisition) or therapeutic (e.g. transcutaneous pacing) functions and~~ may be internal or external and disposable or reusable.

201.3.205**DELIVERED ENERGY**

energy which is delivered through the DEFIBRILLATOR ELECTRODES and dissipated in the PATIENT or in a resistance of specified value

201.3.206**DISCHARGE CIRCUIT**

circuit within the DEFIBRILLATOR which connects the ENERGY STORAGE DEVICE to the DEFIBRILLATOR ELECTRODES. This circuit includes all switching connections between that device and the DEFIBRILLATOR ELECTRODES

NOTE The DISCHARGE CIRCUITS for defibrillation and pacing functions may be separate or combined.

201.3.207**DUMMY COMPONENT**

test replacement for moulded components like transformers, resistors, semiconductors etc.

NOTE The DUMMY COMPONENT has a geometry equal to that of the component it will replace during the test, but provides dielectric isolation. The volume may lack parts of the original components (for example: semiconductor die, transformer cores and windings). The DUMMY COMPONENT makes it possible to test creepage, clearance and dielectric strength with the correct geometry without exceeding the internal maximum voltage of the part being replaced. The DUMMY COMPONENT shall be identical to the component replaced with respect to conductive external details such as metal legs, pins etc.

201.3.208

DEFIBRILLATOR TESTER

instrument capable of measuring the energy output from a CARDIAC DEFIBRILLATOR while generating a simulated ECG output to the CARDIAC DEFIBRILLATOR

201.3.209

ENERGY STORAGE DEVICE

component that is charged with the energy necessary to deliver an electrical defibrillation pulse to the PATIENT

NOTE ~~A capacitor is a typical example of the component.~~ The energy storage devices for defibrillation and pacing functions may be separate or combined.

201.3.210

FREQUENT USE

term used to describe a DEFIBRILLATOR designed to endure more than 2 500 discharges (see 201.103)

201.3.211

INFREQUENT USE

term used to describe a DEFIBRILLATOR designed to endure less than 2 500 discharges (see 201.103)

201.3.212

INTERNAL DISCHARGE CIRCUIT

circuit within the DEFIBRILLATOR which discharges the ENERGY STORAGE DEVICE without energizing the DEFIBRILLATOR ELECTRODES

201.3.213

MANUAL DEFIBRILLATOR

DEFIBRILLATOR capable of being manually operated by the OPERATOR for selection of energy, charging and discharging

201.3.214

MONITOR

part of a DEFIBRILLATOR providing a visual display of the electrical activity of the PATIENT's heart

NOTE The term is used within this particular standard to distinguish such a MONITOR from one which forms a separate ME EQUIPMENT in its own right even in cases where the separate stand-alone monitor is able to provide synchronization signals to the DEFIBRILLATOR, used as basis for AED rhythm recognition detection or providing control signals to the DEFIBRILLATOR.

201.3.215

RHYTHM RECOGNITION DETECTOR

RRD

a system that analyzes the ECG and identifies whether a cardiac rhythm is shockable

NOTE The algorithm in an AED is designed for sensitivity and specificity for the detection of arrhythmias for which a defibrillation shock is clinically indicated. May be referred to as RRD.

201.3.216

SELECTED ENERGY

energy which the defibrillator is intended to deliver, as determined by the setting of a manual control or by an automatic protocol

201.3.217

SEPARATE MONITORING ELECTRODE

electrode applied to the PATIENT for the purpose of monitoring the PATIENT

NOTE These electrodes are not used to apply defibrillation pulses to the PATIENT.

201.3.218

STAND-BY

mode of operation in which the ME EQUIPMENT is operational except that the ENERGY STORAGE DEVICE is not yet charged

201.3.219

STORED ENERGY

energy which is stored in the DEFIBRILLATOR ENERGY STORAGE DEVICE

201.3.220

SYNCHRONIZER

device allowing the DEFIBRILLATOR discharge to be synchronized with a specific phase of the cardiac cycle

201.3.221

PACER

EXTERNAL TRANSCUTANEOUS PACEMAKER

optional circuit within the DEFIBRILLATOR intended to stimulate the heart by a series of electrical pulses via electrodes applied to the PATIENT's skin

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.2 RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

Addition:

201.4.2.101 * Additional RISK MANAGEMENT requirements

MANUFACTURER shall address readiness for use in the RISK MANAGEMENT FILE.

Check compliance by inspection of RISK MANAGEMENT FILE.

201.4.3 ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 * Additional ESSENTIAL PERFORMANCE requirements

Each of the three capabilities listed in Table 201.101, when included in a defibrillator, will be considered ESSENTIAL PERFORMANCE.

Where engineering judgement by the MANUFACTURER specifies performance in excess of ESSENTIAL PERFORMANCE, that performance may be degraded by external factors such as EMC, as long as the RISK MANAGEMENT FILE documents that ESSENTIAL PERFORMANCE is met.

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

Requirement	
Description	(Sub)clause
Deliver defibrillation therapy	201.12.1
Deliver synchronized defibrillation therapy	201.104
Accurately differentiate between shockable and nonshockable rhythms	201.107

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.3 * Ambient temperature, humidity, atmospheric pressure

Addition:

aa) The test required in 201.102.2 and 201.102.3 shall be performed at an ambient temperature of $0\text{ °C} \pm 2\text{ °C}$.

201.5.4 Other conditions

Addition:

aa) Unless otherwise specified in this standard, all tests apply to all kinds of DEFIBRILLATOR types (manual, AEDs, INFREQUENT USE and FREQUENT USE DEFIBRILLATORS).

201.5.8 Sequence of tests

Addition:

The endurance test required in Clause 201.103 shall be performed after the test for excessive temperatures (see B.19 of the general standard).

The tests required in Clauses 201.101, 201.102, 201.104, 201.105 and 201.106 shall be performed after test B.35 of the general standard.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.2 * Protection against electric shock

Amendment:

Delete TYPE B APPLIED PART.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows: